UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI SOUTHERN DIVISION

AMBER COLVILLE; RALPH
ALVARADO; STATE OF
MISSISSIPPI; STATE OF ALABAMA;
STATE OF ARIZONA; STATE OF
ARKANSAS; COMMONWEALTH OF
KENTUCKY; STATE OF
LOUISIANA; STATE OF MISSOURI;
and STATE OF MONTANA,

Civil Action No. <u>1:22cv113 TBM-RPM</u>

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; THE UNITED STATES OF AMERICA,

Defendants.

Plaintiffs,

COMPLAINT

Amber Colville, Ralph Alvarado, and the sovereign States of Mississippi, Alabama, Arizona, Arkansas, Kentucky, Louisiana, Missouri, and Montana bring this civil action against Defendants for declaratory and injunctive relief and allege as follows:

INTRODUCTION

- 1. "[D]istinctions between citizens solely because of their ancestry are by their very nature odious to a free people whose institutions are founded upon the doctrine of equality." *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 215-16 (1995). That "all Men are created equal" is a principle written in the Declaration of Independence and fundamental to who we are as a nation.
- 2. Under our Constitution, "The way to stop discrimination on the basis of race is to stop discriminating on the basis of race." Parents Involved in Cmty. Sch. v. Seattle Sch. Dist. No. 1, 551 U.S. 701, 748 (2007). But according to the most prominent critical race scholar, "The only remedy to present discrimination is future discrimination." Ibram X. Kendi, How to Be an Antiracist 19 (2019). "[T]reating, considering, or making a distinction" based on someone's race is good if it's "antiracist"—meaning it promotes "equity." Id. at 18-19. Because "race-neutral" approaches supposedly do not promote equity, they are actively "racist." Id. at 17. Equity, in turn, means that all racial groups must be "on approximately equal footing" in all things, no matter the cause of the existing disparity. Id.
- 3. Unlike any prior administration, the Biden administration has sided with critical race scholars over the law. The administration is injecting the terms "antiracism" and "equity" into various agency regulations, knowing full well what those terms of art mean—even citing Kendi himself in the Federal Register. *E.g.*, 86 Fed. Reg. 20,349 &

- n.3. And now the administration is injecting these concepts into the one area where they belong the least: medicine.
- 4. The Centers for Medicare and Medicaid Services (CMS) released a final rule that pays doctors more money if they will promulgate an "anti-racism" plan. These anti-racism plans must include a "clinic-wide review" of the doctor's "commitment to anti-racism" based on a definition of race as "a political and social construct, not a physiological one."
- 5. Not only does this Anti-Racism Rule encourage doctors to elevate race over medical treatment in violation of our nation's core principles, but it violates the law. Congress enacted the Medicare Access and CHIP Reauthorization Act of 2015—the statute that creates the Merit-based Incentive Payment System that CMS is changing (MIPS, for short)—to encourage doctors to keep costs down while maintaining the best quality care. It is concerned with care and cost, not race. And by incentivizing doctors to spend time on an activity that CMS concedes is heavily time consuming, the Anti-Racism Rule has doctors elevate creating an "equity plan" over focusing on patient care and wellbeing.
- 6. CMS's rule encourages doctors to go against the principle of racial equality embodied in the Declaration, guaranteed by the Constitution, protected by federal law, and enforced by the Supreme Court. It encourages doctors to elevate faddish theories about race above patient care. It is unlawful, unreasoned, and un-American.

PARTIES

- 7. The individual plaintiffs are Amber Colville and Ralph Alvarado, medical doctors practicing in Ocean Springs, Mississippi, and Winchester, Kentucky, respectively. The individual plaintiffs receive payments from Medicare, are MIPS-eligible clinicians, and participate in the MIPS program. They have not submitted an anti-racism plan to CMS.
- 8. The individual plaintiffs believe that racial discrimination, of any kind, has no place in medicine. They oppose the concepts of "antiracism" and "equity"—terms of art adopted from critical race scholarship—because these concepts inject race-based decisionmaking into medical decisions without any medical justification. The individual plaintiffs believe these concepts are not only bad medicine, but also unlawful and fundamentally un-American. They do not believe that creating these plans is in the best medical interests of their patients, and the time needed to create and implement them would detract from providing real care.
- 9. Because they refuse to submit anti-racism plans, the Anti-Racism Rule places the individual plaintiffs at a direct disadvantage vis-à-vis their competitors. Their competitors can be reimbursed at higher rates, while the individual plaintiffs cannot.
- 10. Separately, the individual plaintiffs are penalized in their improvement activity MIPS score for not submitting what they believe to be unscientific, unethical, and unlawful plans. The Rule takes money out of their practices by hindering their ability to achieve a high score.

- 11. The state plaintiffs are the sovereign States of Mississippi, Alabama, Arizona, Arkansas, Kentucky, Louisiana, Missouri, and Montana.
- 12. The state plaintiffs oppose racial discrimination, of any kind, in medicine. They prohibit racial discrimination in their laws and their agreements with medical-care providers. By encouraging Medicare providers to make medical decisions based on race, the Anti-Racism Rule puts the state plaintiffs in a bind: either enforce their rules against providers who submit "anti-racism" plans (and deprive their citizens of needed care), or stop enforcing their rules barring racial discrimination. Providers who fail to submit these plans, moreover, will get reimbursed at lower rates—increased costs that will fall on beneficiaries like the state plaintiffs and their citizens.
- 13. The state plaintiffs also have a "quasi-sovereign interest" in the "health and well-being" of their citizens, including by protecting them from "the harmful effects of [racial] discrimination." *Alfred L. Snapp & Son, Inc. v. P.R. ex rel. Barez*, 458 U.S. 592, 609 (1982). The Anti-Racism Rule harms that quasi-sovereign interests by encouraging race-based decisionmaking in medicine and decreasing the quality and availability of medical care.
- 14. Defendant Chiquita Brooks-LaSure, sued in her official capacity, is the Administrator of CMS. She signed the final rule challenged in this lawsuit.
- 15. Defendant the Centers for Medicare and Medicaid Services is a federal agency organized under the laws of the United States. CMS is responsible for federally administering Medicare and promulgated the final rule challenged in this lawsuit.

- 16. Defendant Xavier Becerra, sued in his official capacity, is Secretary of the Department of Health and Human Services.
- 17. Defendant United States Department of Health and Human Services ("HHS") is a federal agency organized under the laws of the United States. It is responsible for administering federal healthcare policy and is the cabinet-level Department of which CMS is a part.
 - 18. Defendant United States of America is the federal sovereign.

JURISDICTION AND VENUE

- 19. This Court has subject-matter jurisdiction because this case arises under the Constitution and laws of the United States. *See* 28 U.S.C. §1331; §1346; §1361; 5 U.S.C. §§701-06. An actual controversy exists between the parties within the meaning of 28 U.S.C. §2201(a), and this Court can grant declaratory relief, injunctive relief, and other relief under 28 U.S.C. §§2201-02; 5 U.S.C. §§705-06; and its inherent equitable powers.
- 20. Defendants' final rule constitutes a final agency action that is judicially reviewable under the APA. 5 U.S.C. §704; §706.
- 21. Venue is proper in this Court under 28 U.S.C. §1391(e)(1) because Defendants are United States agencies or officers sued in their official capacities, Dr. Colville is a resident of this judicial district, no real property is involved, and a substantial part of the events or omissions giving rise to the Complaint occurred within this judicial district.

BACKGROUND

I. The Constitution's Prohibition on Racial Classifications

- 22. "In the eyes of government, we are just one race here. It is American." *Adarand*, 515 U.S. at 239 (Scalia, J., concurring in part and concurring in the judgment).
- 23. Consistent with the principles of equality set out in the Declaration, the Constitution forbids discrimination by the federal government against any citizen on the basis of race. *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 215-16 (1995). And the Supreme Court has recognized the "basic principle that the Fifth and Fourteenth Amendments to the Constitution protect *persons*, not *groups*." *Id.* at 227; *see also Grutter v. Bollinger*, 539 U.S. 306, 353 (2003) (Thomas, J., concurring in part and dissenting in part) ("The Constitution abhors classifications based on race, not only because those classifications can harm favored races or are based on illegitimate motives, but also because every time the government places citizens on racial registers and makes race relevant to the provision of burdens or benefits, it demeans us all.").
- 24. The equal-protection component of the Fifth Amendment thus prohibits the federal government from enacting racial classifications. Included within the prohibition on racial classification is a prohibition on distributing benefits based on race. "Individuals who have been wronged by unlawful racial discrimination should be made whole; but under our Constitution there can be no such thing as either a creditor or a debtor race. That concept is alien to the Constitution's focus upon the individual, … and its rejection of dispositions based on race, or based on blood …. To pursue the

concept of racial entitlement—even for the most admirable and benign of purposes—is to reinforce and preserve for future mischief the way of thinking that produced race slavery, race privilege and race hatred." *Adarand*, 515 U.S. at 239 (Scalia, J. concurring in part and concurring in the judgment).

25. The Constitution's abhorrence of racial classification leaves no room for racial decisionmaking seeking to remedy amorphous and poorly defined concepts such as "systematic racism." *See Parents Involved*, 551 U.S. at 748. Instead, "as a general rule, all race-based government decisionmaking—regardless of context—is unconstitutional." *Id.* at 751-52 (Thomas, J., concurring).

II. The Medicare Access and CHIP Reauthorization Act of 2015

Access Act" or "Act") was enacted to implement a new scoring system—called the Quality Payment Program—to determine eligible doctors' reimbursement rates. The Act was a bipartisan compromise negotiated to control Medicare costs and prevent doctors from billing Medicare for services regardless of medical necessity. See House Energy & Commerce and Ways & Means Comms., Section by Section Analysis of H.R. 2 Medicare Access and CHIP Reauthorization Act (Mar. 24, 2015) ("The new system moves Medicare away from a volume-based system towards one that rewards value, improving the quality of care for seniors."); see also Senate Comm. on Finance, Medicare Access and CHIP Reauthorization Act of 2015: Ensuring Successful Implementation of Physician Payment Reforms, S. Hrg. 114-679 (July 13, 2016).

- 27. The Act directs HHS to establish a Merit-based Incentive Payment System to incentivize cost-control, performance, and engagement in certain activities. Pub. L. 114-10 §101 (codified at 42 U.S.C. §1395w-4). "The MIPS program aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care." 86 Fed. Reg. at 65375. CMS employs MIPS to "pay for health care services in a way that drives value by linking performance on cost, quality, and the patient's experience of care." 86 Fed. Reg. at 65375.
- 28. Recipients eligible for MIPS are subject to a payment adjustment based on their performance in four categories: quality, resource use, improvement activities, and promoting interoperability. 42 U.S.C. §1395w-4(q)(2)(B). The improvement-activities category is at issue here—it is given fifteen percent weighting in the MIPS adjustment.
- 29. The Act defines "clinical practice improvement activity" to mean "at least the following: (I) ... expanded practice access such as same day appointments ... (II) ... population management, such as monitoring health conditions of individuals to provide timely health care intervention ... (III) ... care coordination, such as timely communication of test results ... (IV) ... beneficiary engagement, such as the establishment of care plans for individuals with complex care needs ... (V) patient safety and practice assessment, such as through use of clinical or surgical checklists ... (VI) ... participation in an alternative payment model." 42 U.S.C. §1395w-4(q)(2)(B)(iii).

- 30. The Act also directs HHS to issue a request for information (RFI) to solicit recommendations for identifying improvement activities and specifying criteria. For purposes of the RFI, the Act defines "clinical practice improvement activities" as "an activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes." 42 U.S.C. §1395w-4(q)(2)(C)(v)(III).
- 31. Clinicians who do well in the performance categories receive a positive payment adjustment.
- 32. 99.9999 percent of MIPS-eligible clinicians participate in the program. 86 Fed. Reg. at 65375. The program covers a broad array of providers: physicians (including doctors of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, and optometry); osteopathic practitioners; chiropractors; physician assistants; nurse practitioners; clinical nurse specialists; certified registered nurse anesthetists; physical therapists; occupational therapists; clinical psychologists; qualified speech-language pathologists; qualified audiologists; registered dietitians or nutrition professionals; clinical social workers; and certified nurse midwives. Individuals who are eligible to participate in MIPS must participate in MIPS.

33. The term "equity" does not appear in the Act. The only time the Act references race or ethnicity is in its directive to establish an educational campaign to encourage racial and ethnic minorities to receive chronic care services. 42 U.S.C. §1395w-4 note.

III. Implementation of the Medicare Access Act in the Obama and Trump Administrations

- 34. In November 2016, President Obama's CMS issued a final rule implementing the MIPS program. 81 Fed. Reg. 77008 (Nov. 4, 2016). In this rule, CMS added "achieving health equity" as a clinical improvement activity. CMS theorized that it was appropriate to add this new category because (1) it is important and may require targeted effort to achieve and so should be recognized when accomplished; (2) it supports national priorities and programs, such as Reducing Health Disparities; and (3) it encourages "use of plans, strategies, and practices that consider the social determinants that may contribute to poor health outcomes." 81 Fed. Reg. at 77189.
- 35. But the Obama Administration did not adopt several specific recommendations for establishing specific equity activities related to race, such as "an activity that encourages referrals to a clinical trial for a minority population." *Id.* at 77195. CMS also rejected a comment suggesting that it "pursue additional approaches to the quality performance category to advance health equity and reward MIPS eligible clinicians who promote health equity including: adding measures stratified by race and ethnicity or other disparity variable, and developing and adding a stand-alone health equity measure

as a high priority measure for which clinicians can receive a bonus point." *Id.* at 77293. The baseline was to collect data regarding racial disparities—not incentivize race-based actions by clinicians.

36. The Trump CMS similarly rejected suggestions for "the use of an equity bonus ... to address the additional costs for serving traditionally underserved populations." 83 Fed. Reg. 16440, 16584-85 (Apr. 16, 2018).

IV. The Biden Administration's Anti-Racism Rule

- 37. On January 20, 2021, President Biden issued Executive Order 13985, directing the Executive Branch to address systematic racism and promote "equity," which the Order defines as "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment." 86 Fed. Reg. 7009. The Order further directs agencies to identify policies undermining "equity" and change policies to promote "equity."
- 38. Expressly relying upon the Executive Order and its definition of equity, CMS published a rule on July 23, 2021 proposing to, among other things, create a new improvement activity under the equity banner "create and implement an anti-racism plan." 86 Fed. Reg. 39104, 39346 (July 23, 2021). The two-sentence rationale for this new activity declares that "it is insufficient to gather and analyze data by race." *Id.* Instead, an anti-racism plan "emphasizes systematic racism is the root cause for differences in health outcomes between socially defined racial groups." *Id.*

- 39. On November 19, 2021, CMS published the final rule, which adopts the proposed rule's anti-racism plan activity. In the final rule, CMS offers the same two-sentence rationale: "This improvement activity acknowledges it is insufficient to gather and analyze data by race, and document disparities by different population groups. Rather, it emphasizes systemic racism is the root cause for differences in health outcomes between socially defined racial groups." 86 Fed. Reg. 64996, 65384 (Nov. 19, 2021).
- The final rule's appendix specifies that "create and implement an anti-rac-40. ism plan" will be a "new improvement activity" given "high" weighting falling under the "achieving health equity" improvement activity subcategory. Id. at 65969. The appendix states that "[t]he plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one." Id. The appendix adds that "[t]he plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care." For good measure, "[t]he MIPS eligible clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying

explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color."

41. In the two-paragraph "rationale" for the racism plan requirement, CMS cites to no statutory authority whatsoever, nor does it explain how the new activity furthers the goals of the Medicare Access Act. Instead, CMS states that the authority for the racism plans are Executive Order 13985. See id. ("The proposed activity aimed to address systemic inequities, including systemic racism, as called for in Executive Order 13985."). CMS asserts that the activity will potentially "improve clinical practice or care delivery ... because it supports MIPS clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care." Id. The anti-racism plans are "intended to help" doctors "move beyond analyzing data to taking real steps to naming and eliminating the causes of the disparities identified." Id. CMS made this activity "high-weighted because MIPS eligible clinicians will need considerable time and resources to develop a thorough anti-racism plan that is informed by data, and to implement it throughout the practice or system." Id.

CLAIMS FOR RELIEF COUNT I The Anti-Racism Rule is Contrary to Law

- 42. Plaintiffs repeat and incorporate each of the allegations above.
- 43. The final rule is final agency action reviewable under the APA.

- 44. Pursuant to the APA, a "reviewing court shall ... hold unlawful and set aside agency action ... found to be ... not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. §706(2)(A), (C).
 - 45. The Anti-Racism Rule violates the Medicare Access Act.
- 46. The Medicare Access Act defines "clinical practice improvement activity" to mean "at least the following: (I) ... expanded practice access such as same day appointments ... (II) ... population management, such as monitoring health conditions of individuals to provide timely health care intervention ... (III) ... care coordination, such as timely communication of test results ... (IV) ... beneficiary engagement, such as the establishment of care plans for individuals with complex care needs ... (V) patient safety and practice assessment, such as through use of clinical or surgical checklists ... (VI) ... participation in an alternative payment model." 42 U.S.C. §1395w-4(q)(2)(B)(iii).
- 47. When adding new improvement activities pursuant to 42 U.S.C. §1395w-4(q)(2)(C)(v)(III), CMS must not drastically depart from the specific enumerated activities of §1395w-4(q)(2)(B)(iii). Those specifically enumerated activities come nowhere close to authorizing race or equity related activities. Instead, they focus on practical considerations like same-day appointments, test results, and patient safety. Accordingly, the Anti-Racism Rule is not authorized by the Medicare Access Act.
- 48. Moreover, CMS ignored statutory factors by failing to demonstrate how the Anti-Racism Rule is likely to "improv[e] clinical practice or care delivery." 42 U.S.C. §1395w-4(q)(2)(C)(v)(III). And CMS does not even attempt to demonstrate how the

Anti-Racism Rule "is likely to result in improved outcomes." *Id.* Because CMS failed to make these statutorily required findings, the Anti-Racism Rule is contrary to the Medicare Access Act.

- 49. CMS also fails to identify "relevant eligible professional organizations and other relevant stakeholders" suggesting the Anti-Racism Rule. The Act requires that "relevant eligible professional organizations and other relevant stakeholders identify" that the improvement activity "improv[es] clinical practice or care delivery." 42 U.S.C. §1395w-4(q)(2)(C)(v)(III). But CMS does not cite to any such professional organization or stakeholders who have examined and verified that the Anti-Racism Rule will improve clinical practice or care delivery. Accordingly, CMS's promulgation of the Anti-Racism Rule violates the process set out by the Medicare Access Act.
- 50. CMS's interpretation also violates the Social Security Act's overriding purpose of patient well-being by elevating nonstatutory equity policy concerns above Congress's commands. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993); *see also Biden v. Missouri*, 142 S. Ct. 647, 650 (2022) (noting that under the Act HHS's "core mission [] is to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety").
- 51. CMS also improperly elevates Executive Order 13985's policy directives above Congress's commands in the Medicare Act and in the Social Security Act, whose focus is on patient care, not equity. *Id.*; see also California v. Bernhardt, 472 F. Supp. 3d at

605 ("A president's Executive Order cannot 'impair or otherwise affect' statutory mandates imposed on [an agency] by Congress." (citing *In re Aiken Cty.*, 725 F.3d 255, 260 (D.C. Cir. 2013) (Kavanaugh, J.)).

COUNT II The Anti-Racism Rule is Arbitrary and Capricious

- 52. Plaintiffs repeat and incorporate each of the allegations above.
- 53. The APA commands courts to "hold unlawful and set aside agency action, findings, and conclusions found to be [] arbitrary, capricious, an abuse of discretion." 5 U.S.C. §706(2)(A). "The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021).
- 54. The Provision is arbitrary and capricious for several independently sufficient reasons.

CMS Provides No Rationale for the Provision

Solution 55. CMS does not even attempt to provide a rationale for the Anti-Racism Rule aside from a couple of conclusory sentences. CMS's entire explanation for the "improving clinical practice or care delivery" statutory factor, 42 U.S.C. §1395w-4(q)(2)(C)(v)(III), and for the separate "likely to result in improved outcomes" statutory factor, is as follows: "We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes ... because it supports MIPS eligible clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care." 86 Fed. Reg. at 65969. Such

conclusory statements are not a substitute for actually considering the statutory factors and explaining the decision reached. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) ("[C]onclusory statements do not suffice to explain [an agency's] decision."); *State v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) ("Stating that a factor was considered ... is not a substitute for considering it.""); *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (courts "do not defer to the agency's conclusory or unsupported suppositions"). Because CMS fails to explain its decision to adopt the Anti-Racism Rule and simply parrots the statutory language, its decision is arbitrary and capricious. *See Music Choice v. Copyright Royalty Bd.*, 970 F.3d 418, 429 (D.C. Cir. 2020) ("[A]n agency's ipse dixit cannot substitute for reasoned decisionmaking.").

56. CMS's citation to Executive Order 13985 is no substitute for reasoned decisionmaking either. *See, e.g.*, *Louisiana v. Biden*, 543 F. Supp. 3d 388, 414 (W.D. La. 2021) ("A decision supported by no reasoning whatsoever in the record cannot be saved merely because it involves an Executive Order.").

CMS Ignores the Purpose of the Medicaid Act & Medicare Access Act

- 57. The Anti-Racism Rule is directly contrary to the central objective of relevant federal statutes—patient wellbeing and access to care. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993).
- 58. CMS nowhere demonstrates that promulgating a plan to undo purported systematic societal racism will actually contribute to improved patient care. The types of patient care relevant under the Act are things like shorter wait times and better care

outcomes. 42 U.S.C. §1395w-4(q)(2)(B)(iii). Not undoing supposed broader societal racism.

59. Making matters worse, CMS admits that "clinicians will need considerable time and resources to develop a thorough anti-racism plan that is informed by data, and to implement it throughout the practice or system." 86 Fed. Reg. at 65969. In other words, CMS admits that promulgating the plan will take time away from actual patient care and pursuing specifically enumerated activities such as the "timely communication of test results" and "the establishment of care plans for individuals with complex care needs." 42 U.S.C. §1395w-4(q)(2)(B)(iii).

CMS Points to No Evidence of Systematic Racism Justifying the Provision

- 60. "Rules are not adopted in search of regulatory problems to solve; they are adopted to correct problems with existing regulatory requirements that an agency has delegated authority to address." N.Y. Stock Exch. LLC v. SEC, 962 F.3d 541, 556-57 (D.C. Cir. 2020). CMS provides no evidence whatsoever of the systematic racism in the medical field that it purports to address nor evidence that "anti-racism" plans will do anything to address it.
- 61. Although agencies have some leeway in making predictive judgments, a regulation must be based on something more than "sheer speculation." *Sorenson Comme'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014); *see also Bus. Roundtable v. SEC*, 647 F.3d 1144, 1149-50 (D.C. Cir. 2011) (agency must "support its predictive judgments" with actual evidence).

- 62. Because CMS "presented no evidence that [the problem it purported to solve] is ever seen in practice," *Bus. Roundtable*, 647 F.3d at 1150, it has failed to set out a reasoned justification for the Anti-Racism Rule, *see N.Y. Stock Exch.*, 962 F.3d at 556 (regulations "must be designed to address identified problems"); *Music Choice v. Copyright Royalty Bd.*, 970 F.3d 418, 429 (D.C. Cir. 2020 ("[R]ational decisionmaking ... requires more than an absence of contrary evidence; it requires substantial evidence to support a decision.").
- 63. And CMS's citation to the Executive Order does not substitute for reasoned decisionmaking. *See, e.g.*, *Louisiana v. Biden*, 543 F. Supp. 3d at 414; *California v. Bernhardt*, 472 F. Supp. 3d at 605 ("A president's Executive Order cannot 'impair or otherwise affect' statutory mandates imposed on [an agency] by Congress." (citing *In re Aiken Cty.*, 725 F.3d 255, 260 (D.C. Cir. 2013) (Kavanaugh, J.))).

CMS Ignores Medical Science

- 64. Not only did CMS fail to point to an accepted basis in the medical community for the Anti-Racism Rule in violation of 42 U.S.C. §1395w-4(q)(2)(C)(v)(III), but its decision also goes against medical science.
- 65. For example, CMS states that the plan should define race as "a political and social construct, not a physiological one." 86 Fed. Reg. at 65969. But doctors have recognized that this dichotomy will discourage genetic testing and actually worsen health disparities: "A lot of conditions'—such as Tay-Sachs, which disproportionately

impacts Ashkenazi Jews, and triple-negative breast cancer, which disproportionately affects black women—'vary based on genetics. We're talking about matters of life and death here." Sibarium, *Doctors Warn New Medical School Guidance Would Lead to Unqualified Physicians and Unscientific Medicine*, Wash. Free Beacon (Nov. 29, 2020); *see also id.* ("Singer's warning echoes the argument that five black professors in March made in the New England Journal of Medicine, where they described genetic denialism as 'a form of naive color blindness' that would 'perpetuate and potentially exacerbate disparities." (quoting Akinyemi Oni-Orisan, *Embracing Genetic Diversity to Improve Black Health*, 384 N. Engl. J. Med. 1163, 1165 (2021))).

66. CMS presents no countervailing evidence. But see Music Choice v. Copyright Royalty Bd., 970 F.3d 418, 429 (D.C. Cir. 2020 ("[R]ational decisionmaking ... requires more than an absence of contrary evidence; it requires substantial evidence to support a decision.").

CMS Does Not Acknowledge or Explain its Change in Position

- 67. When an agency changes positions, it must "display awareness that it is changing position" and demonstrate "good reasons for the new policy." *FCC v. Fox Television Stations Inc.*, 556 U.S. 502, 515 (2009). CMS did neither.
- 68. As an initial matter, CMS's Anti-Racism Rule represents a change in policy. CMS has traditionally adhered to a data collection approach and has declined to implement high-weighted race-based performance activities. In the past, CMS declined to adopt several specific recommendations for establishment of specific equity activities

related relace such as "an activity that encourages referrals to a clinical trial for a minority population." 81 Fed. Reg. at 77189. It also rejected a comment suggesting that it "pursue additional approaches to the quality performance category to advance health equity and reward MIPS eligible clinicians who promote health equity including: adding measures stratified by race and ethnicity or other disparity variable, and developing and adding a stand-alone health equity measure as a high priority measure for which clinicians can receive a bonus point." *Id.* at 77293. The Trump CMS also rejected suggestions for "the use of an equity bonus ... to address the additional costs for serving traditionally underserved populations." 83 Fed. Reg. 16440, 16584-85 (Apr. 16, 2018). The baseline was clear: collect data regarding racial disparities without implementing specific incentivization activities based on race.

69. The Anti-Racism Rule thus represents a change in position. Yet CMS does not acknowledge that it is changing position and does not engage with its previous positions. Such "sub silentio" changes in position are arbitrary and capricious. Moreover, as discussed above, CMS provides no reasons whatsoever for its change, much less "good reasons." Because CMS "does not acknowledge [its] prior position, does not point to any evidence that [its] concerns have been ameliorated, and does not present any new reasons for adopting the amended audit procedure that it previously rejected," its change in position is arbitrary and capricious. *Music Choice*, 970 F.3d at 429.

The Rule Ignores the Constitution's Prohibition of Racial Categorization and Federal Law's Prohibitions on Discrimination

- 70. The Anti-Racism Rule also ignores the principle of racial equality embodied by the Declaration, guaranteed by the Constitution, and confirmed by the Supreme Court.
- 71. The Rule encourages doctors to make race-based decisions in their practices. This is abhorrent to the equality guaranteed by the Constitution. An agency's decision to incentivize private parties to make racial classifications goes against the racial equality principle embodied in the Declaration, Constitution, precedent, and myriad federal laws. A policy at odds with a principle that is so integral to the fabric of the American republic and its laws is arbitrary and capricious.
- 72. Moreover, the Anti-Racism Rule creates tension with several statutory prohibitions on discrimination, subjecting doctors to potentially conflicting obligations and incentives. *See, e.g.*, 42 U.S.C. §2000d ("No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.").
- 73. This irreconcilable tension between the Constitution and statutes on the one side and the Anti-Racism Rule on the other is, to put it mildly, an "important aspect of the problem" that CMS entirely failed to consider. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

PRAYER FOR RELIEF

Plaintiffs request an order and judgment:

- a. declaring, under 28 U.S.C. §2201, that the Anti-Racism Rule violates the Medicare Access Act;
- b. declaring under 28 U.S.C. §2201, that the Anti-Racism Rule is arbitrary and capricious;
- c. vacating the Anti-Racism Rule;
- d. enjoining enforcement of the Anti-Racism Rule or providing the same benefits to those who do not submit anti-racism plans that satisfies the Rule as those who do; and
- e. granting Plaintiffs all other appropriate relief.

Dated: May 5, 2022 Respectfully submitted,

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